

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
22 January 2004 (22.01.2004)

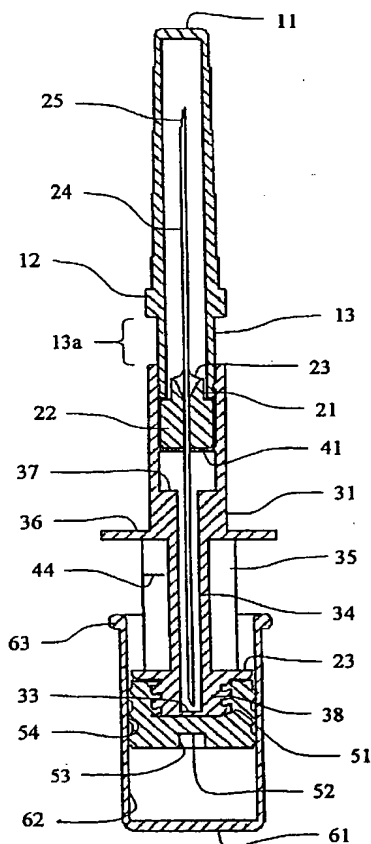
PCT

(10) International Publication Number
WO 2004/006986 A3

- (51) International Patent Classification⁷: **A61M 5/00**
- (21) International Application Number:
PCT/US2003/021799
- (22) International Filing Date: 14 July 2003 (14.07.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
RM02A000378 15 July 2002 (15.07.2002) IT
- (71) Applicants (for all designated States except US): **EURO 3 S.R.L.** [IT/IT]; Via del Conservificio, 1, I-06083 Bastia Umbra (IT). **BOSHEARS & BOSHEARS CONSULTING, INC.** [US/US]; 7633 E. 63rd Place, Suite 530, Tulsa, OK 74133 (US).
- (72) Inventor: **DIONIGI, Francesca** [IT/IT]; Via delle Fornaci, 1, I-06034 Foligno (IT).
- (74) Agent: **CATALANO, Frank, J.**; Gable & Gotwals, 100 West 5th Street, 10th Floor, Tulsa, OK 74103 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,

[Continued on next page]

(54) Title: ACTIVATION-BASED INJECTION DEVICE



(57) Abstract: An activation-based injection device includes an activation unit (1, 2, 3), a vial unit (5) containing a drug and a needle (2) with an inner point (26) which never comes in contact with the external environment. The device is activated by a simple axial shift of the needle-shield (1) against the activation head (3). The latter is transparent and contains a window (45) of lower thickness. This allows the user to check the exact position of the needle hub (21) as a proof of tamper evidence, allowing the user to immediately determine whether the device has been previously activated or tampered with and if there is a risk that the drug has been contaminated.

WO 2004/006986 A3



SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— with amended claims and statement

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations
- of inventorship (Rule 4.17(iv)) for US only

(88) Date of publication of the international search report:
1 July 2004

Date of publication of the amended claims and statement:
26 August 2004

Published:

- with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BT09 Rec'd PCT/PTO 14 JAN 2005

AMENDED CLAIMS

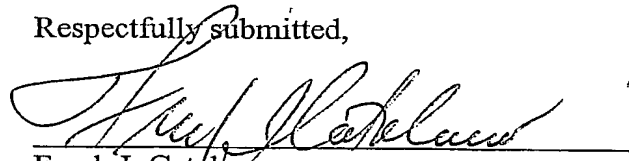
[received by the International Bureau on 23 June 2004 (23.06.2004);
new claim 20 added ; remaining claims unchanged (1 page)]

20. . A device for injecting a drug into a patient comprising:
- an activation head (3) open at one end thereof and closed by a pierceable membrane (33) at another end thereof;
 - a needle-shield (1) closed at one end (11) thereof and open at a base (13) thereof, said base (13) fitting and sliding in a rail (31) of said activation head (3);
 - a rigid vial (5) having a reservoir containing the drug and having a sliding plunger (4) hermetically sealing said vial, said plunger adapted for attachment to said another end of said activation head (3) for making direct contact between a pierceable membrane of said plunger (52) and said pierceable membrane of said activation head (33);
 - a needle (2) having a double-pointed cannula (24) secured to a hub (21) disposed inside said rail of said activation head (3); and
 - a needle-shield (1) slidable inside said activation head (3) from said initial resting position to a final activation position for acting on said hub (21) and sequentially piercing said pierceable membranes (33 and 52) with said inner point (26) of said needle (2) and connecting said cannula (24) to said reservoir of said vial (5).

STATEMENT UNDER ARTICLE 19(1)

This statement specifically refers to the Amendment of Claims Under Article 19 filed on even date herewith for International Application Number PCT/US03/21799 entitled ACTIVATION-BASED INJECTION DEVICE. Applicants submit this Amendment of Claims to further define patentable aspects of the invention. The claim amendments are within the scope of the invention disclosure, and the amendments are expected to have no impact on the description or drawings.

Respectfully submitted,



Frank J. Catalano

Registration No. 25,836

PTO Customer No. 07303

GABLE & GOTWALS

100 West 5th Street, 10th Floor

Tulsa, Ok 74103 USA

Tel: (918) 595-4963

Fax: (928) 595-4990